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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of )  
Miller et al. ) Group Art Unit: 1643  
Serial No. 09/483,434 ) Examiner: Leffers, G., Jr.  
Filed: January 14, 2000 )  
For: METHODS FOR DELIVERING )  
BIOLOGICALLY ACTIVE MOLECULES )  
INTO CELLS )

ELECTION UNDER RESTRICTION REQUIREMENT

Honorable Commissioner of  
Patents and Trademarks  
Washington, D.C. 20231

NEEDLE & ROSENBERG, P.C.  
Suite 1200, The Candler Building  
127 Peachtree Street, N.E.  
Atlanta, Georgia 30303-1811

July 18, 2000

Sir:

This is responsive to the Office Action dated May 19, 2000, wherein restriction of the claims and election of species in the above-identified application are required. The Office Action requires restriction to one of the following two groups of claims: Group I, which the Examiner designates as claims 1-3 and 7, drawn to a method of delivery of a biologically active molecule; Group II, which is designated as claims 4-5, drawn to a method of delivering a biologically active molecule to cells of a tissue or organ in a human body; Group III, which is designated as claim 6, drawn to a method of delivering an oligonucleotide to a cell with PEI; Group IV, which is designated as claim 8, drawn to a method of delivering a marker to a cell; Group V, which is designated as claims 9-10, drawn to a composition comprising a nucleic acid-PEI-avidin complex; and Group VI, which is designated as claims 11-14, drawn to cells comprising a covalently linked surface receptor molecule. Applicants provisionally elect Group I with traverse.

With regard to the required election of species upon the provisional election of the claims of Group I, Applicants provisionally elect the species oligonucleotides, with traverse. The following claims of Group I are readable on this provisional species election: 1, 2, 3, and 7.

Applicants request that the restriction requirement be reconsidered because the Examiner has not shown that a serious burden would be required to examine all the claims. In particular, Applicants request that the separation of claims into Group I, II and III be reconsidered.

M.P.E.P. § 803 provides:

If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions. (*Emphasis added.*)

Thus, for a restriction requirement to be proper, the Examiner must satisfy the following two criteria: (1) the existence of independent and distinct inventions (35 U.S.C. § 121); and (2) that the search and examination of the entire application cannot be made without serious burden.

See M.P.E.P. § 803.

The Examiner has not shown that the second requirement has been met. Specifically, the Examiner has not shown that it would be a serious burden to search and examine the three groups together. The groups are closely related in that they involve methods for delivery molecules to cells, which may be part of a tissue or organ. In particular, claim 7, now in Group I, depends on claim 7, now in Group III, so it would seem logical to include Group III in Group I. A main difference in Group I and II is simply the molecule being delivered, namely a biologically active molecule or an oligonucleotide-PEI complex. Due to this very close relationship, little or no additional burden would be required to search and examine Groups I, II and III together. Indeed,

the subject matter of the claims of Groups I, II and III would require searching the same two classes and subclasses for all three groups (Class 514, subclass 1,2 44 and Class 435, subclass 440), which would not constitute a serious burden upon the Examiner. Furthermore, examining these three groups of claims together would eliminate the necessity of prosecuting multiple, separate, yet intimately related, applications. Thus, this criterion of M.P.E.P. § 803 as set forth above has not been satisfied, because the Examiner has not shown that it would be a serious burden to search and examine these three groups of claims of this invention together.

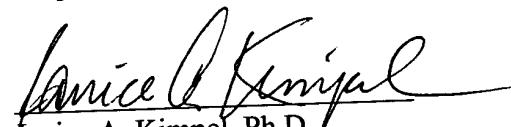
For the reasons stated above, applicants respectfully assert that restriction of the claims as set forth by the Examiner would be contrary to promoting efficiency, economy and expediency in the U.S. Patent and Trademark Office (PTO) and further point out that restriction by the Examiner is discretionary (M.P.E.P. § 803.01). Thus, applicants respectfully request that the claims in Groups I, II and III of this application be examined together. Consequently, reconsideration and modification or withdrawal of the restriction requirement is requested. With regard to the required election of species, all claims in Groups II and III are readable on the provisional species election made hereinabove.

Applicants acknowledge that, upon allowance of a generic claim, applicants will be entitled to consideration of claims to additional species.

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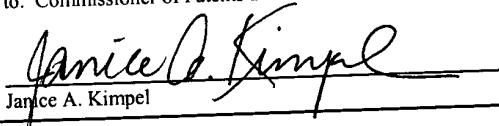
A check in the amount of \$110.00 and a Request for Extension of Time are enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

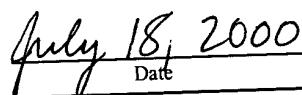
Respectfully submitted,

  
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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks Washington, D.C. 20231, on the date shown below.

  
Janice A. Kimpel

  
Date